

GOVERNMENT OF GUÅHAN



DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES

DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT

123 Chalan Kareta, Mangilao, Guåhan 96913-6304

Felix P. Camacho
Governor

J. Peter Roberto, A.C.S.W.
Director

Michael W. Cruz, M.D.
Lieutenant Governor

PRESS RELEASE

2010- 048 _____

Expanded Recall on the McNeil Consumer Healthcare Over the Counter Products

The Division of Environmental Health (DEH) of this department, in coordination with the U.S. Food and Drug Administration (USFDA), would like to inform the public that the department is keeping abreast and responding to the recent expansion and addition of five product lots regarding the voluntary recall of McNeil Consumer Healthcare's over-the-counter (OTC) products.

This recall is a follow-up to the product recall that McNeil Consumer Healthcare announced on January 15th, 2010 and is being taken because the products were inadvertently omitted from the initial recall action. McNeil Consumer Healthcare identified the omission and informed the U.S. Food and Drug Administration (FDA) of its decision to add these product lots to the recall list. All these products were produced before the January 15th, 2010 recall.

The January 15th, 2010 recall was initiated as a result of consumer complaints of a musty or moldy odor that has since been linked to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA). After a thorough investigation, it was determined that the source of TBA was the result of a breakdown of a chemical that is applied to wood used to build wooden pallets that transport and store product packaging materials. Since January, McNeil Consumer Healthcare has continued to analyze and evaluate TBA and has shared that information with the FDA. This further analysis confirms that the risk of serious adverse medical events is remote.

The additional lots involved are four product lots of BENADRYL® ALLERGY ULTRATAB™ TABLETS, 100 count, sold in the U.S., and one product lot of EXTRA STRENGTH TYLENOL® Rapid Release Gels, 50 count, sold in the U.S., Trinidad and Tobago, Bermuda, and Puerto Rico. The product lot numbers for the recalled products can be found on the side of the bottle label.

The full recalled products are listed below:

Product Name	Product Form	Lot Number	NDC Number	UPC Code
BENADRYL Allergy ULTRATAB Tablets 100 count	Ultratab Tablet	AJA008, ADA194, ABA022, ABA264	50580-226-10	312547170338
EXTRA STRENGTH Tylenol Rapid Release Gels 50 count	Rapid Release Gelcap	ASA202	50580-488-50	300450488503

To date, the DEH has determined that one Pay-Less Supermarket, (Sinajana location) was found to be carrying the implicated recalled product. Sinajana Pay-Less Supermarket store has voluntarily removed the products from shelves. The DEH is continuing to work with other retailers to determine the availability and the names of each recalled commodity. As more information is learned DEH will notify the public.

Consumers who purchased the affected products should stop using the product and contact McNeil Consumer Healthcare for instructions on a refund or replacement by calling 1-888-222-6036 (Monday-Friday 8:00 a.m. – 8:00 p.m. Eastern Time, and Saturday – Sunday 9:00 a.m. – 5:00 p.m. Eastern Time) or via website at <http://www.mcneilproductrecall.com>. Consumers who have concerns or questions should contact their healthcare provider.

Any adverse reactions may be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/safety/medwatch/default.htm. You may also contact the Division of Environmental Health at 735-7221. Dangkolo Na Si Yu'us Ma'ase!


J. PETER ROBERTO, ACSW
Director



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JUN 25 2010

PRESS RELEASE

#2010 – 049

Voluntary Recall of Three Varieties of “SpaghettiOs” With Meatballs

The Department of Public Health and Social Services, in coordination with the U.S. Department of Agriculture (USDA), would like to inform the public that the department is keeping abreast and responding to the recent voluntary recall involving approximately 15,000,000 pounds of three varieties of “SpaghettiOs with Meatballs” canned products manufactured by Campbell Soup Supply Company, LLC of Paris, Texas. These products are being recalled because it’s possible the product was under-processed during production.

The problem was discovered through a routine warehouse inspection by the company and its subsequent investigation. The USDA has not received any reports of illness from consumption of these products.

The Campbell’s products were distributed nationwide to wholesalers and retailers. The three products involved in the voluntary recall include: 1) “SpaghettiOs” with Meatballs (14.75 ounce can) bearing product code “U5,” 2) “SpaghettiOs” A to Z with Meatballs (14.75 ounce can) bearing product code “4N,” and 3) “SpaghettiOs” Fun Shapes with Meatballs (14.75 ounce can) bearing product code “KS”. The product codes are located on the bottom of the can. The products subject to recall bear the establishment number “EST4K”, as well as a “Use By” date between June 2010 and December 2011 ink-jetted on the bottom of each can. These products were manufactured between December 2008 and June 2010 and distributed to wholesalers and retailers nationwide. No other Campbell’s products are impacted by this recall.


To date, the Division of Environmental Health has determined that the implicated products were available at the following facilities:

1. Pay-Less Supermarkets, (Micronesia Mall, Mangilao, Dededo and Yigo locations);
2. 7-Day Supermarkets (Yona and Harmon locations);
3. Island Fresh IGA supermarket (Chalan Pago location); and
4. Jae Hoon Corporation wholesaler who distributed the products at these retail stores:
 - a. New Happy Mart (Barrigada);
 - b. Choi’s Market (Maite);
 - c. Kathy’s Mini Mart (Merizo);
 - d. Tumon 7 Mart (Tumon);
 - e. Hanna Market (Dededo);
 - f. California Market (Tamuning);
 - g. Super Mart (Mangilao);
 - h. Mobil (Yona);
 - i. Aguon’s Store (Barrigada); and
 - j. Mobil (Ipan)

All affected products were voluntarily removed from their store shelves.

The department has not received any local reports of injuries or illnesses associated with the consumption of this recalled commodity. Consumers who have purchased any of the implicated products listed above are urged to stop using the product immediately. Consumers with questions or concerns about the recall may contact Campbell's Hotline at 1-(866) 495-3774, the USDA Meat and Poultry Hotline at 1-(888) 674-6854, or USDA's website at www.AskKaren.gov.

For any questions, please contact the Division of Environmental Health at 735-7221.



J. PETER ROBERTO, ACSW
Director